

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings includes changes to Figs. 2a, 2d, 3 and 5. These sheets, which include Figs. 2a, 2d, 3 and 5, replace the original sheets including Figs. 2a, 2d, 3 and 5.

In Figure 2a, previously omitted element 13 has been added.

In Figure 2d, the reference numbers have been enlarged to make them legible and amended to avoid overlaps with different elements in other drawings. The changes to the reference numbers have also been reflected in the replacement pages 13-16 of the specification discussed above.

In Figure 3, reference numbers 17 and 21 have been amended to be 317 and 321 to avoid overlaps with different elements in other drawings.

In Figure 5, previously omitted element 26 has been added.

Attachments:

Drawing Replacement Sheets

Annotated Sheets Showing Changes

### REMARKS

This paper is responsive to the Office Action mailed September 14, 2006, in the above-captioned application. In response to the Office Action, the specification, abstract, drawings and claims 1, 2, 4, 6-10, 12-14, 16 and 17 have been amended as described above. Claims 15, 18, and 20 have been canceled without prejudice or disclaimer. No new matter has been added.

#### Information Disclosure Statement

A supplemental information disclosure statement in compliance with 37 C.F.R. §1.98(a)(3) including the non-English reference DE 42 08 677 A1 has been submitted herewith. The Examiner's consideration of this reference is respectfully requested.

#### Drawings

The drawings have been amended to correct the deficiencies identified by the Examiner. Therefore, withdrawal of the objection to the drawings is respectfully requested.

#### Specification

A replacement Abstract has been submitted in which "means" have been replaced with "mechanism." Therefore, withdrawal of the objection to the Abstract is respectfully requested.

With respect to the informalities in the specification identified by the Examiner, these informalities have been corrected as discussed above. Therefore, withdrawal of this objection is respectfully requested.

With respect to the alleged failure of the specification to provide proper antecedent basis for the claims, reference to the following portions of the specification is provided.

(1) "an oblique surface being provided on the dispensing means": See specification at page 5, paragraphs 2 and 3, stating that "[t]he oblique surface can be provided on either or both of the protrusion or the dispensing means. The oblique surface forms a contact surface between the operating means, i.e., the protrusion, and the dispensing means, i.e., the piston rod.

“In principle, it would also be possible to shift the tip of the protrusion along an oblique surface provided on the dispensing means. Said oblique surface may preferably be arranged on the facing side of the piston rod. . . .”

(2) “a guiding means being provided to guide when the injection needle is placed onto or removed from the product container”: See specification at page 18, paragraph 2, in which the use of sleeve 27 to guide positioning of a needle cap to enable removal of a used needle or attachment of a new needle is disclosed with reference to Fig. 8.

(3) “a setting element projecting through an opening in the casing of the injection device and dimensions of the opening limiting movement of the settling element in accordance with a predetermined dose amount”: The “setting means” is no longer recited in the claims (see amendments above). The releasing means recited, for example, in amended claims 6 and 17, is described, for example, on pages 16 and 17 of the specification with reference to Fig. 5.

Claim Objections and Rejection Under 35 U.S.C. §112

The informalities in claims 6-9 and 12 identified by the Examiner have been corrected by the amendments set forth above. The terms identified by the Examiner in claims 10 and 13 have proper antecedent basis. Claim 18 has been canceled without prejudice or disclaimer. Therefore, withdrawal of the objections to the claims is respectfully requested.

In addition, claims 4, 12 and 13 have been amended to address the Examiner’s rejection of these claims under §112. Therefore, withdrawal of the rejection under §112 is respectfully requested.

Rejection under 35 U.S.C. § 102

(1) Claims 1-3 and 14-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ronvig (U.S. Patent No. 5,433,352). Ronvig describe a liquid dispenser in which a toothed bar 20 is attached to a piston 8 for delivery of a fluid via injection needle 13. Coupled to the toothed rod 20 is a latch 25, which is pivotally coupled to a u-shaped lever arm 22. The latch 25 engages teeth on the toothed rod. By depressing the lever arm 22, which at its front end engages with the toothed bar (via latch 25), the latch 25 pushes the toothed bar 20 a predetermined distance

toward the front end of the dispenser, causing dispensing of the liquid through syringe 13. When the lever arm 22 is disengaged, the spring effect caused by deformation of the area in which the latch 25 is connected to the lever arm 22 causes the lever arm moves back to the starting position at an angle to the casing. Col. 4, lines 34-44.

In contrast to the present invention as recited in amended claims 1 and 14, Ronvig does not teach or suggest an operating means having a lever portion and a lever arm portion provided at a fixed angle with respect to one another. In Ronvig, assuming *arguendo* that the latch 25 and lever arm 22 form the operating means, the latch 25 and lever arm 22 are necessarily pivotable with respect to each other in order to perform the dispensing operation of the Ronvig device (see col. 4, lines 34-44). Moreover, Ronvig does not teach or suggest a lever arm portion that extends from the lever portion along the injection device to an attachment point at which the operating means pivots in a radial direction relating to the device as recited in amended claims 1 and 14. The lever arm 22 and latch 25 are both attached to the pivot point in Ronvig, which is contrary to the invention recited in amended claims 1 and 14. Additionally, Ronvig does not teach or suggest the claimed protrusion, wherein pivoting of the operating means causes movement of protrusion along the oblique contact surface between the operating means and the displacement means to displace the dispensing means to deliver the product. The movement of the latch 25 is along the longitudinal axis of the syringe (i.e., along the toothed rod), and not along a surface oblique to the longitudinal axis of the syringe as recited in amended claims 1 and 14.

Also, Ronvig does not teach or suggest the moveable releasing element for releasing a dose, wherein the releasing element projects through an opening in the casing and the dimensions of the opening limiting movement of the setting element in accordance with a predetermined dose amount as recited in amended claim 17.

For at least these reasons, amended claims 1, 14 and 17 are believed to be patentable over Ronvig.

Also, claims 2, 3, 5, and 15-16 depend from amended claims 1 and 14 respectively and are believed to be patentable for at least those reasons set forth above with respect to amended claims 1 and 14.

(2) Claims 1 and 3-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Haber et al. (U.S. Patent No. 5, 505,704). Haber describes a one-piece glass prefilled syringe system in which a jacket is provided for a conventional glass syringe. The jacket is used to position the syringe for injection. An injection may be given by pushing upper body member 20 of the jacket toward lower body member 19, thereby pushing the plunger of the syringe toward the injection end of the syringe. After use, the jacket is folded to encompass the syringe for safe disposal.

In contrast to the present invention as recited in amended claim 1, Haber does not teach or suggest an operating means with lever portion and lever arm portion wherein the lever arm portion is provided at a fixed angle to the lever portion as recited in amended claim 1. Instead, assuming *arguendo* that the body members of the jacket in Haber constitute the operating means, the angle between the lower and upper body members is necessarily alterable to perform the functions of the jacket. Moreover, the upper and lower body of the Haber jacket are not pivotable in a radial direction relative to the casing of the injection device. Instead, the upper and lower body members in Haber are only pivotable with respect to one another around hinge 22, for example, as illustrated by the arrows in Figs. 3-5 of Haber. Moreover, Haber does not disclose the claimed protrusion wherein movement of protrusion along the oblique contact surface between the operating means and the displacement means displaces the dispensing means to deliver the product. In Haber, the plunger flange 14 is locked into a plunger flange receptacle 48 formed through the upper body member 20 of the jacket 18. Col. 5, lines 8-11. Thus, there is no movement between the upper body member 20 and the plunger flange 14.

For at least these reasons, Haber does not teach or suggest the invention recited in amended claim 1, and amended claim 1 is believed to be patentable over Haber.

Additionally, claims 3-5 depend from amended claim 1 and are believed to be patentable over Haber for at least those reasons set forth above with respect to amended claim 1.

(3) Claims 1-3, 5-9, and 14-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cosmai (U.S. Patent No. 4, 850,967). Cosmai describes a portable endermic injector having a trigger assembly 13 in which an actuator 40 is pressed against an annular lever 41 by a spring 43. The annular lever is connected to a push button 38 by a pin 45. If the push

button 38 is operated, the lever 41 is displaced and pushes the actuator forward. Several variations of the triggering assembly are illustrated in Figs. 3-6 of Cosmai.

In contrast to the invention recited in amended claims 1 and 14, Cosmai does not teach or suggest an operating means having a lever portion and a lever arm portion provided at a fixed angle with respect to one another. There is no comparable structure in Cosmai: the push button 38 and pin 45 do not meet the structural or functional description of the claimed operating means, and the trigger mechanisms 66 and 162 enable operation of the device by being pushed axially toward the injection end of the device, and not pivoted in a radial direction relative to the device as described in amended claims 1 and 14. Moreover, Cosmai does not teach or suggest a lever arm portion that extends from the lever portion along the injection device to an attachment point at which the operating means pivots in a radial direction relating to the device as recited in amended claims 1 and 14. The Cosmai operating assemblies do not contain any comparable structure. Additionally, Cosmai does not teach or suggest the claimed protrusion, wherein pivoting of the operating means causes movement of protrusion along the oblique contact surface between the operating means and the displacement means to displace the dispensing means to deliver the product.

For at least these reasons, amended claims 1 and 14 and dependent claims 2, 3, 5, 8 and 16 are believed to be patentable over Cosmai.

Also, in contrast to the invention recited in amended claims 6 and 17, Cosmai does not teach or suggest an injection device having a dosing means including a releasing element for setting a dose amount, wherein the releasing element projects through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the amount of the dose. The Cosmai device does not include any such setting feature. The Examiner seems to suggest that the size of the opening through which releasing element 56 in Cosmai extends somehow determines the size of the dose. However, there is no teaching or suggestion of this feature in Cosmai. Therefore, amended claims 6 and 17 are believed to be patentable over Cosmai.

Claims 7 and 9 depend from amended claim 6 and are believed to be patentable for at least those reasons set forth above with respect to amended claim 6.

Claim 19 depends from amended claim 17 and is believed to be patentable for at least those reasons set forth above with respect to amended claim 17.

(4) Claims 10, 11 and 13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gillespie, III (U.S. Patent No. 6,387,078). Gillespie describes an automatic mixing and injecting apparatus including a spring-operated plunger assembly driven by driver spring 500 and a syringe return spring 505.

In contrast to the injection device described in amended claim 10, Gillespie does not teach or suggest a sleeve that slides axially with respect to the holder or product container to generally surround said injection needle in an advanced position. Instead, the housing nose 105 is permanently joined by threading or bonding with the housing cap 120, the housing midsection 110, and the housing tubular section 115 to form the housing 100. Col. 4, lines 12-16. Thus, Gillespie does not provide any teaching or suggestion of the slidable sleeve of amended claim 10, and claim 10 is believed to be patentable over Gillespie.

Claim 11 depends from amended claim 10 and is believed to be patentable over Gillespie for at least those reasons set forth above with respect to amended claim 10.

In addition the features of amended claim 10, amended claim 13 also recites that the sleeve guides the positioning of a needle cap used to attach or detach the injection needle of the injection device. There is no teaching or suggestion of this function in Gillespie. For this reason in addition to those discussed above with respect to amended claim 10, amended claim 13 is believed to be patentable over Gillespie.

(5) Claims 10, 11 and 13 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hommann et al. (U.S. Patent Appl. No. Pub. No. 2003/0144632).

With respect to amended claims 10 and 11, a declaration under 37 C.F.R. §1.132 has been provided to remove Hommann as prior art under 35 U.S.C. § 102(e).

With respect to amended claim 13, Hommann does not teach or suggest a sleeve that guides the positioning of a needle cap used to attach or detach the injection needle of the injection device. Consequently, amended claim 13 is believed to be patentable over Hommann.

Rejection under 35 U.S.C. § 103

(1) Claims 8, 9, and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ronvig in view of Burroughs. (U.S. Patent No. 6,001,089). Burroughs describes a recyclable multiple dose medication dispensing device including a dial dosing assembly.

However, neither Ronvig, nor Burroughs, nor the combination thereof teaches or suggests the injection device recited in amended claim 1, from which claims 8, 9, and 12 depend. As discussed above with respect to amended claim 1, Ronvig does not teach or suggest an operating means having a lever portion and a lever arm portion provided at a fixed angle with respect to one another. Moreover, Ronvig does not teach or suggest a lever arm portion that extends from the lever portion along the injection device to an attachment point at which the operating means pivots in a radial direction relating to the device as recited in amended claim 1. Additionally, Ronvig does not teach or suggest the claimed protrusion, wherein pivoting of the operating means causes movement of protrusion along the oblique contact surface between the operating means and the displacement means to displace the dispensing means to deliver the product. The movement of the latch 25 is along the longitudinal axis of the syringe (i.e., along the toothed rod), and not along a surface oblique to the longitudinal axis of the syringe as recited in amended claim 1. Burroughs also does not teach or suggest these features recited in amended claim 1. Therefore, claims 8, 9, and 12, which depend from amended claim , are believed to be patentable over the applied combination of references.

(2) Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ronvig in view of Hommann et al.

However, as discussed above with reference to amended claim 17, from which claim 19 depends, Ronvig does not teach or suggest the moveable releasing element for releasing a dose, wherein the releasing element projects through an opening and the dimensions of the opening limiting movement of the setting element in accordance with a predetermined dose amount as recited in amended claim 17. Hommann also does not teach or suggest any such feature. Therefore, claim 19 is believed to be patentable over the combination of Ronvig and Hommann.



This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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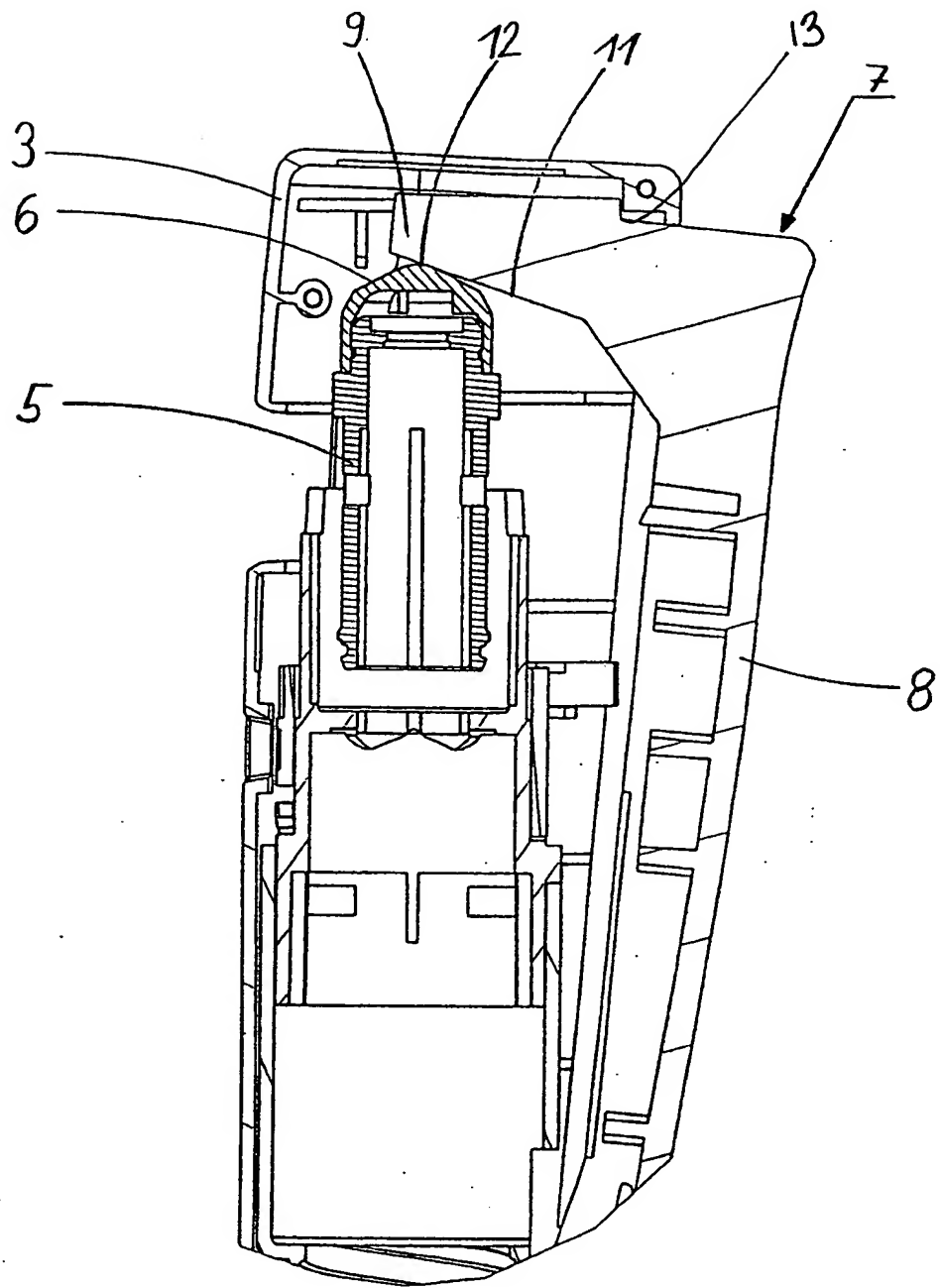
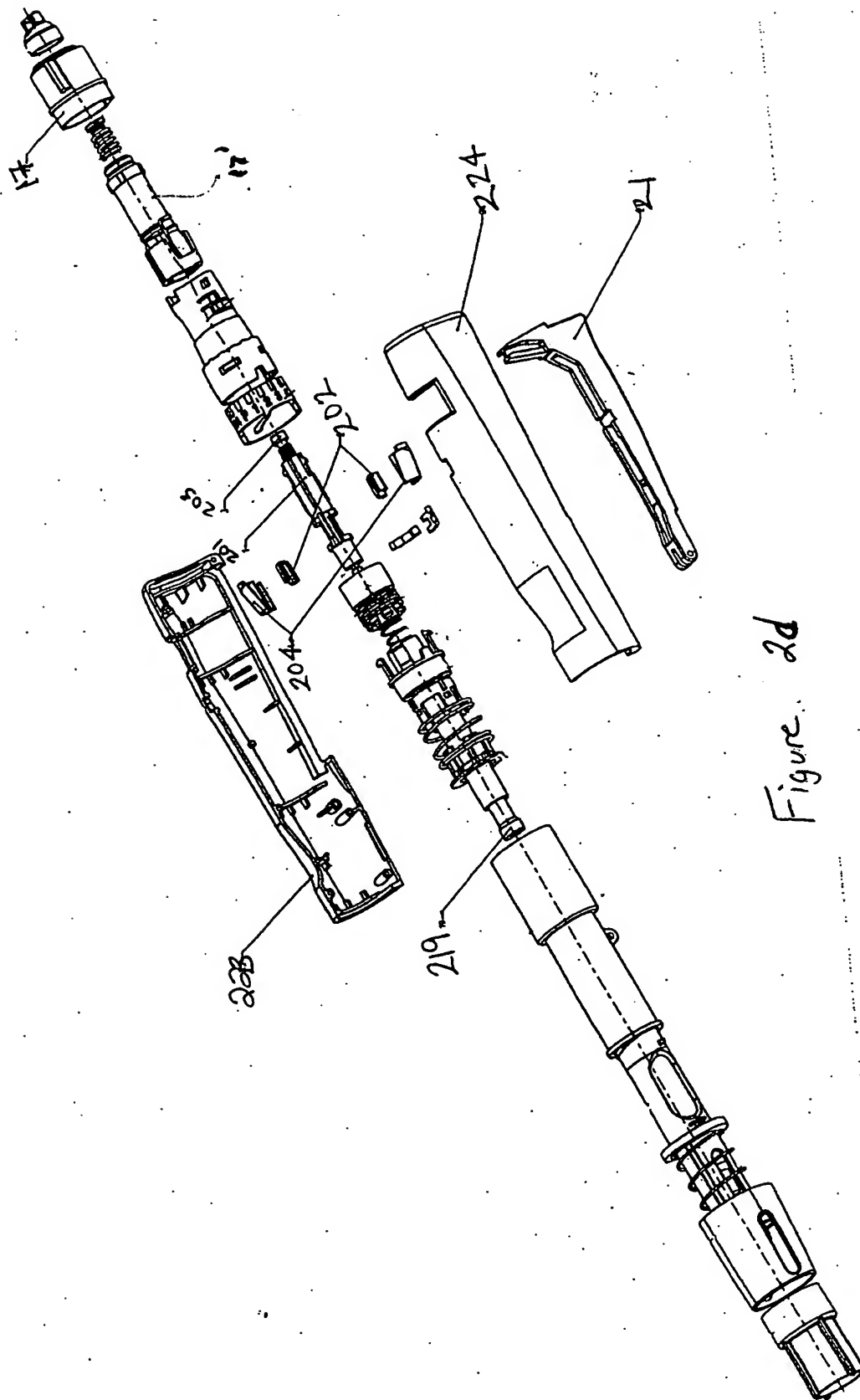


Fig. 2a

Annotated Drawing



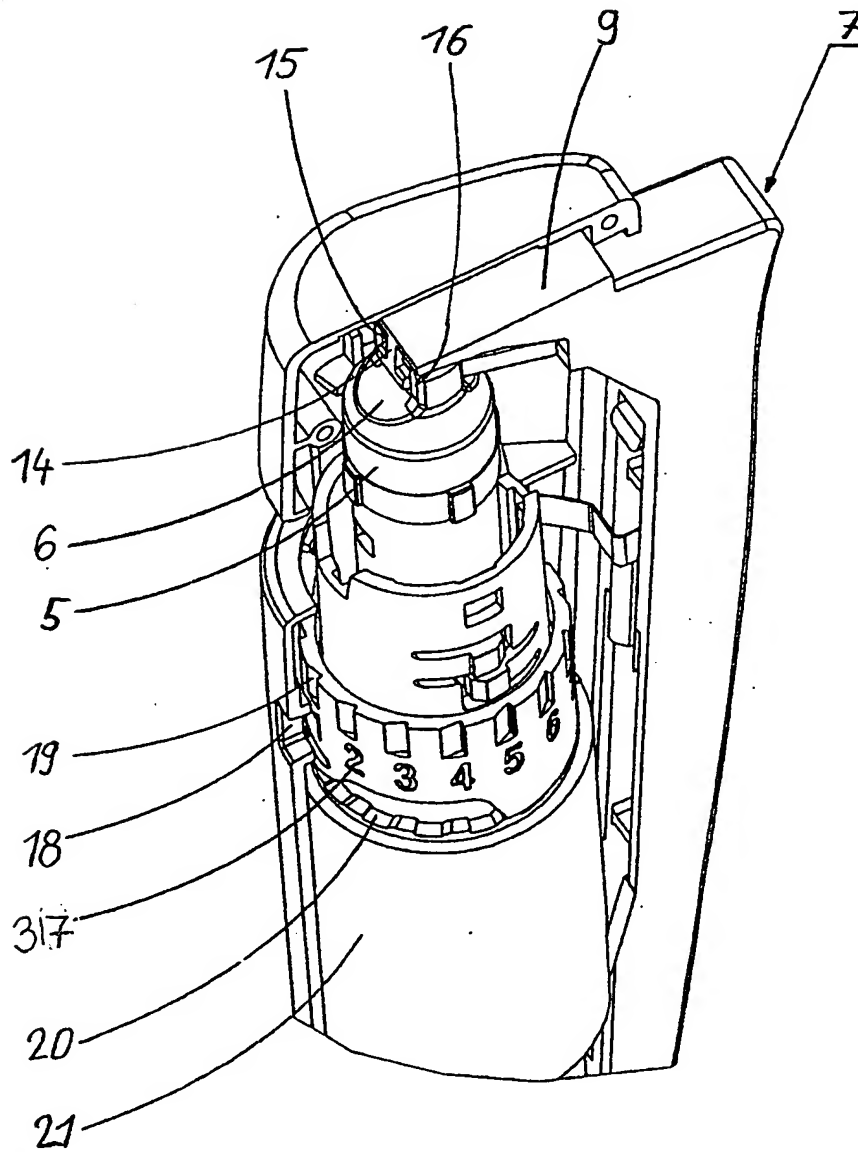


Fig. 3

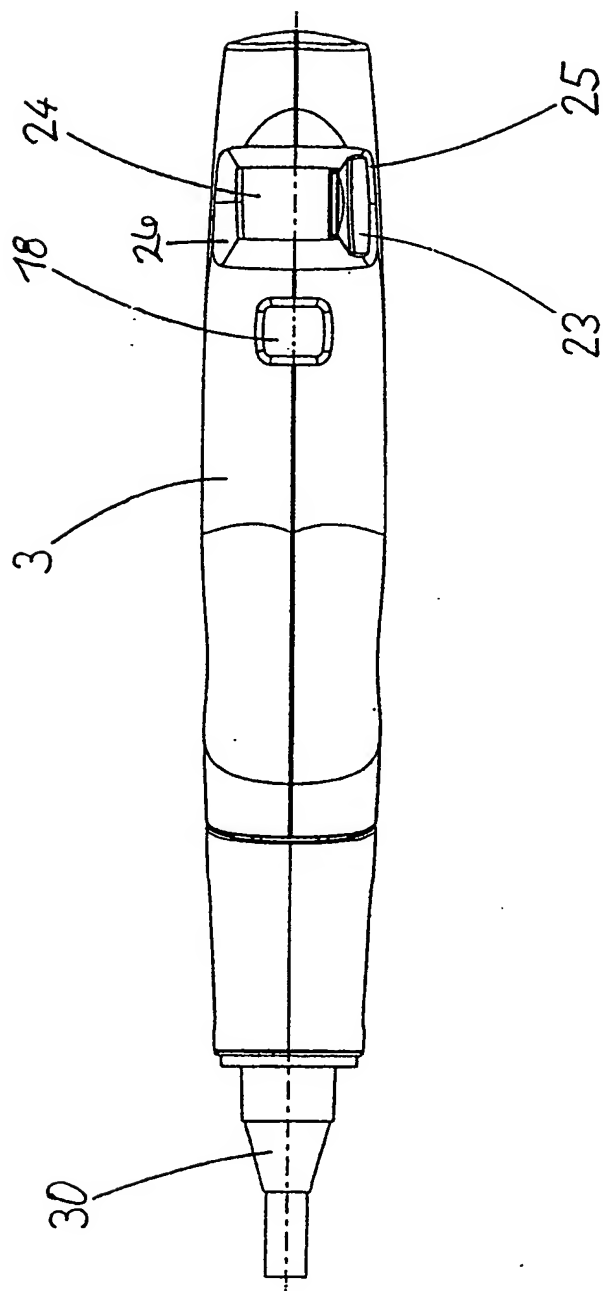


Fig. 5